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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaimant.

Case No.: 3:21-cv-03496-AMO-LB

REPLY IN SUPPORT OF MOTION OF INTUITIVE SURGICAL, INC. TO EXCLUDE TESTIMONY OF PHILIP J. PHILLIPS

Hearing To Be Renoticed
Hearing Place: Courtroom 10

Judge: The Honorable Araceli Martínez-Olguín

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I. INTRODUCTION AND STATEMENT OF ISSUE

In its motion to exclude the testimony of SIS's "FDA" expert, Philip J. Phillips (Dkt. No. 121) ("Mot."), Intuitive demonstrated that Phillips' opinion that SIS acted reasonably in not seeking 510(k) clearance from FDA before engaging in commercial activities involving EndoWrists modified to extend their number of uses, is irrelevant. Mot. at 2, 4–5, 8–9. Intuitive also demonstrated that Phillips' opinions that SIS and Iconocare were not engaged in remanufacturing under FDA regulations are impermissible legal opinions. *Id.* at 2, 5–6, 9–13. And Intuitive demonstrated that all of his opinions are unreliable for numerous reasons, including that they are untethered from virtually all of the relevant evidence. *Id.* at 2–8, 10–14. SIS's opposition (Dkt. No. 143) ("Opp.") fails to meet its burden to demonstrate that Phillips' opinions pass muster under *Daubert*.

To begin, SIS does not even try to establish that the "reasonableness" of SIS's actions, efforts, or beliefs is relevant to any issue in this case, including whether SIS's activities require FDA clearance. Phillips admits that the focus of FDA's determinations about the applicable regulatory pathway is on the activities an entity performs on a device, not the entity's intent. Even if Phillips' intent-based reasoning were the result of a reliable analysis (which it is not), his opinion that SIS's conduct was "reasonable" is simply irrelevant.

SIS's attempt to avoid the bar on experts offering legal opinions fares no better. SIS concedes that Phillips is offering the opinion "that SIS's activities were not remanufacturing as currently defined…." Opp. at 3. SIS even stresses that Phillips has "come to that conclusion definitively with zero doubt in his mind," *id.*, but does not attempt to harmonize that opinion with Phillips' other opinion that "it is not possible to reach a definitive legal determination, one way or the other." *Id.* at 5. The key point is that all of these opinions, as well as his opinion that Iconocare's activities do not constitute remanufacturing, are Phillips' interpretation of the law.

SIS also fails to meet its burden to show that Phillips' opinions are reliable. SIS offers no meaningful explanation for Phillips' failure to address the numerous and consistent statements from FDA that directly contradict his opinion. Nor does SIS offer relevant citations – legal or factual – for its argument that Phillips was justified in dismissing every single relevant statement by FDA because they were (as SIS asserts) "non-public and non-binding assertions of low level FDA employees." *Id.* at 2.

And ultimately SIS concedes, as it must, that Phillips either does not know, or did not attempt to apply FDA regulations to, the actual activities that SIS and Iconocare undertook when modifying used EndoWrists to extend their use counters.

As to Phillips' opinions about SIS's counterclaims, SIS does not even attempt to defend Phillips' reliance on conclusory statements from SIS's complaint, his concession that at least one of the statements attributed to Intuitive was not false or misleading but *truthful*, or his departure from his ordinary practice (clearly required here) of considering partially-quoted statements in context. Perhaps most tellingly, SIS also makes no attempt to explain how Phillips can reliably opine *both* that there is uncertainty and ambiguity about FDA regulations *and* that Intuitive's interpretation of those regulations – an interpretation consistent with FDA's interpretation – is false and misleading.

II. ARGUMENT

SIS has not met its burden to establish the admissibility of Phillips' opinions. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993). SIS cannot persuasively deny that Phillips has impermissibly applied "law to the facts of [the] case" and purports to describe the "parties' legal rights, duties and obligations under the law." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058–59 (9th Cir. 2008). SIS also has not shown that Phillips formed his opinions through a reliable methodology reliably applied to the facts of this case. *See United States v. Valencia-Lopez*, 971 F.3d 891, 898 (9th Cir. 2020). Nor has SIS shown that Phillips' opinions are based on a complete review of the record, including a serious evaluation of the evidence. *Smith v. Ill. Dep't of Transp.*, 936 F.3d 554, 558–59 (7th Cir. 2019); *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176–77 (N.D. Cal. 2007).

A. Phillips' Opinion That SIS's Efforts and Beliefs about Applicable Regulatory Requirements Were "Reasonable" is Irrelevant and Unreliable.

SIS has offered nothing to establish that Phillips' opinion that SIS made an "objectively reasonable" attempt to conform to applicable regulatory requirements is relevant to any issue in this case. Although SIS argues that relevance "simply requires that the evidence logically advance a material aspect of the party's case," Opp. at 4, SIS never actually identifies a "material aspect" of any party's case that this opinion "advances." SIS offers no authority for the proposition that the purported

"objective reasonableness" of a company's actions has any bearing, for example, on whether those actions satisfy FDA regulatory requirements. Merely calling SIS's intent a "central issue," *id.* at 4 n.4, does not make it so.

Nor does SIS demonstrate that Phillips' "reasonableness" opinion is reliable. Neither Phillips nor SIS has explained how it could possibly be "objectively reasonable" for SIS to decide not to seek FDA clearance when SIS made no effort to evaluate whether such clearance was required. *See* Opp. at 3; Lazerow Dec. (Dkt. No. 121.1) Ex. 3 at 46:12–15, 61:20–24. It is not "objectively reasonable" to attempt to comply with complex federal regulations by sticking one's head in the sand.

Phillips also does not explain how he thinks FDA regulations apply to the actual instrument modifications at issue in this case. SIS is wrong that Phillips addressed that issue "in detail." Opp. at 3. He did nothing of the sort. SIS points to Phillips' discussion with Greg Posdal as the principal basis for Phillips' understanding of SIS's activities, *id.* at 4 n.4, but Phillips' own recitation of that discussion confirms that Posdal did not describe for him the specific modifications that were actually performed to reset EndoWrist use counters or the resulting changes to those devices. Lazerow Dec. Ex. 1 ¶¶ 84–85.[1] Instead, Phillips asked about, and Posdal discussed, SIS's general *intent* to, for example, "repair" the instruments "as needed" to "meet OEM specifications." *Id*. Phillips repeatedly bases his opinions on this general intent, rather than on any evaluation of the modifications that were actually performed in pursuit of that alleged intent. *E.g.*, *id.* ¶¶ 100–01, 109. Confusingly, he even cites this general "intent" to avoid confronting unnamed "opposing experts," who Phillips appears to understand did in fact base their opinions on the actual modifications and the resulting changes to the instruments. *Id.* ¶ 109.

Phillips could not have been clearer in his deposition that a company's intent has no impact on whether its activities constitute remanufacturing under FDA regulations; the focus is instead on the activities actually performed. *See* Lazerow Dec. Ex. 2 at 396:8–397:11; Lazerow Supp. Dec. Ex. 17 at 261:11–20 (FDA makes its decisions as to whether a company is engaged in remanufacturing "*based on the activities* that are actually being performed on the device" (emphasis added)); *id.* at 87:11–21

[1] SIS does not identify the "other evidence" on which Phillips supposedly relied. Opp. 3-4 n.4. And SIS ignores Intuitive's point that Phillips does not show how the unidentified evidence affected his opinion. *Compare* Mot. at 5 n.2 *with* Opp. at 3 n.4.

(company must "determine what *activities* the company is engaged in and how FDA regulates those *activities*" (emphasis added)). Yet he does not attempt to apply FDA regulations to the "activities" SIS was selling, only to the vague, hoped-for effect of those activities. He does not even cite evidence that SIS's supposed purpose – returning the instruments to "OEM specifications" – was ever achieved. Even if the "reasonableness" of SIS's attempt to comply with FDA regulatory obligations were a relevant issue in this case, Phillips lacks a reliable basis for this opinion.

B. Phillips' Opinion that SIS Is Not a "Remanufacturer" is an Impermissible Legal Conclusion.

SIS's attempt to characterize Phillips' opinions as focused on the "reasonableness" of SIS's actions and beliefs is a transparent effort to evade the bar on an expert opining on the law. SIS's brief does nothing to establish that Phillips' opinion "that SIS is not a remanufacturer, as that term is defined by FDA," Opp. at 2 (quoting Lazerow Dec. Ex. 1 at 42–43) – or his conflicting opinion that "it is not possible to reach a definitive legal determination, one way or the other," *id.* at 5 – is anything other than an impermissible legal conclusion. SIS does not respond to the case law cited by Intuitive that precludes experts from testifying as to issues of law. *Compare* Mot. at 9 *with* Opp. at 4–6.

That case law has only gotten stronger since Intuitive filed its motion. In *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, 2023 WL 2973038, at *15–17 (S.D.N.Y. Mar. 28, 2023), the court granted a motion to exclude an FDA expert who planned to testify that "drugs that comply with FDA's labeling and approval requirements can be and are legally imported whether commercially or by individuals for their own personal use" and "drugs that comply with FDA's approval requirements except for labeling or packaging differences may be imported under FDA's drug labeling exemptions." The court rejected the argument that the expert was not testifying to the ultimate issue of whether the enterprise was "completely or almost completely geared toward facilitating illegality," and instead found that the expert's opinion usurped the court's role in determining "the purely legal question of whether personal importation is permissible under U.S. law," because the opinion "directly state[s] what the law is as it relates to personal pharmaceutical importation." *Id.* at *16–17.[2] Like the FDA expert in

[2] The *PharmacyChecker* court went on to determine as a matter of law that the "competition" allegedly prevented by the defendant was unlawful, contrary to the opinion of the plaintiff's expert, and granted summary judgment for defendants based on the absence of antitrust injury. 2023 WL 2973038, at *30.

PharmacyChecker, Phillips is offering opinions that purport to "dictate what the law is." *Id*. at *17. That is the proper role of the Court, not a retained expert. *See Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004) ("[I]nstructing the jury as to the applicable law is the distinct and exclusive province of the court.").

SIS likewise offers nothing to distinguish the on-point decisions of the two federal courts in Florida that excluded the opinions of FDA experts regarding the definition of "remanufacturing" and the applicability of FDA regulations to the modification of EndoWrists – the very same conduct at issue here. *See* Lazerow Dec. Exs. 6, 7. Phillips' opinions are exactly what those courts warned against: ultimate legal opinions as to whether companies complied with applicable FDA regulations, including opinions that contradict FDA's own stated views. *See* Lazerow Dec. Ex. 6 at 8, 16. SIS does not address the decision in the *Restore* case (Lazerow Dec. Ex. 7) at all. Opp. at 5–6. And although SIS mentions the *Rebotix* case, it does not grapple with the decision cited by Intuitive (Lazerow Dec. Ex. 6). Instead, SIS points to a different decision that does not address the admissibility of expert testimony. *See* Opp. at 6. Moreover, the decision SIS cites further underscores that the determination of whether a company's activities constitute "remanufacturing" is a legal issue unfit for the jury. That decision held that if *the FDA* determined whether a company's modifications to EndoWrist use counters "constitute[s] 'remanufacturing'" or "require[s] Section 510(k) clearance," that court would have resolved the case on summary judgment – *not* preserved the issues for a jury. *Id.* at 6 & n.6 (quoting Order, ECF No. 187, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 8:20-cv-2274 (M.D. Fla. Aug. 10, 2022)).[3]

[3] Intuitive believes that the *Rebotix* court erred in treating this legal question as one that it could not decide, even on the record as it existed then. Notably, all parties in both cases pending before this Court have sought summary judgment on this issue. The record on FDA's position has continued to evolve since the *Rebotix* court issued its order, further confirming that FDA *does* view the modification of EndoWrists to reset their use counters as "remanufacturing" requiring FDA clearance. The additional record includes the FDA's clearance for Iconocare's reset process in September 2022 – an action that further demonstrates FDA's view that such clearance, and the substantial effort FDA had to expend to provide it, is necessary – and FDA's creation of a new product code for a "computer controlled instrument" that has been "remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer." FDA, QSM Product Classification Code, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QSM.

Nor can SIS escape the consistent case law barring expert testimony on legal questions by pointing to opinions in the report of Intuitive's FDA expert, Christy Foreman. Opp. at 5. SIS did not move to exclude Foreman's opinions. And Intuitive has made clear that it will not offer legal opinion testimony from Foreman if Phillips cannot offer such testimony. Mot. at 9 n.4.[4]

C. Phillips' Opinion that SIS Is Not a "Remanufacturer" is Not Reliable.

Phillips' opinion is also not the result of a reliable methodology reliably applied to the record evidence in this case. SIS bears the burden of establishing both that "the reasoning or methodology underlying" Phillips' testimony is "valid," *Valencia-Lopez*, 971 F.3d at 900, and that Phillips genuinely grappled with the evidence in this case, *Smith*, 936 F.3d at 558–59. SIS has done neither. In its opening brief, Intuitive demonstrated that Phillips disregarded all of FDA's statements over the course of nearly a decade on how the agency views modifications made to EndoWrists to reset their use counters. Mot. at 10–11. There is an obvious tension – unaddressed by SIS – between that treatment of the evidence and Phillips' admission at his deposition that he would ordinarily "certainly consider [statements that FDA officials made about the regulatory status of an activity] in rendering opinions, yes." Lazerow Supp. Dec. Ex. 17 at 28:2–10. SIS offers no credible explanation for Phillips' departure from that usual, common-sense methodology in this case.

Instead, SIS implies that it was appropriate for Phillips to dismiss the numerous relevant FDA statements because they are "non-public and non-binding assertions of low level FDA employees" without "delegated legal authority to render a final, policy decision binding on the entire FDA and the public." Opp. at 2; *see also id.* at 5–8. SIS cites no authority showing that FDA employee communications have no regulatory effect. And this argument still does not explain why Phillips departed from his usual methodology of considering on-point statements by FDA officials. *See* Lazerow Supp. Dec. Ex. 17 at 28:2–29:8. More importantly, neither SIS nor Phillips points to any statements by

[4] SIS is wrong that Phillips conducted "essentially the same analysis" as Foreman. Opp. at 5. Unlike Phillips, Foreman exhaustively examined the evidence of FDA's communications and actions in dealing with entities involved in modifying EndoWrists. *See, e.g.*, Lazerow Dec. Ex. 4 ¶¶ 217–35.

FDA – public or non-public, legally binding or not legally binding[5] – to suggest that the consistent, unambiguous statements by those allegedly "low level FDA employees" were wrong.

Ultimately, the arbitrary nature of Phillips' opinion is evident on the face of SIS's brief. SIS concedes that Phillips has opined *both* that: (i) the FDA definition of "remanufacturer" is not clear; and (ii) there is "zero doubt in his mind" that SIS does not meet the FDA definition of "remanufacturer." Opp. at 3. SIS does not even attempt to explain how such "unsupported, self-contradicted" testimony complies with *Daubert*. *See Loy v. Rehab Synergies, LLC*, 558 F. Supp. 3d 402, 408 (S.D. Tex. 2021). Neither of Phillips' 'because-I-say-so' opinions on this point is admissible.

D. Phillips' Opinion that Iconocare Is Not Engaged in Remanufacturing is an Impermissible and Unreliable Legal Conclusion.

Phillips' opinion that Iconocare's 510(k) clearance does not require 510(k) clearance for the modifications SIS was selling is based on his conclusion – ultimately no more than an assumption – that the modifications that Iconocare made to EndoWrists do not constitute "remanufacturing" requiring FDA clearance. *See* Lazerow Dec. Ex. 1 ¶ 121. Even if, contrary to the record, Phillips knew what modifications Iconocare made, this is just another attempt by Phillips to offer a legal opinion. SIS makes no meaningful effort to demonstrate otherwise. Instead, SIS aims for another target, suggesting that Phillips' legal conclusion about Iconocare is *relevant* to this case, Opp. at 10, but even then, SIS cannot show that Phillips' *legal* opinions will "aid the jury in resolving a *factual* dispute." *Daubert*, 509 U.S. at 591 (emphasis added) (internal quotation omitted).

SIS also cannot demonstrate that Phillips' opinion is reliable. Indeed, the fact that Phillips feels he can opine that Iconocare is not a remanufacturer is stunning – not only because the FDA disagrees –

[5] SIS asks the Court to discount the consistent statements of numerous FDA officials that the activity at issue is remanufacturing requiring FDA clearance because the officials allegedly did not have "any delegated legal authority to render a final, policy decision binding on the entire FDA and the public." Opp. at 2. A "final," binding "policy" decision is not required for an FDA regulation to apply to a remanufacturing activity. Moreover, Phillips never grapples with the facts that (a) all FDA statements on this question have been consistent for nearly a decade and (b) those statements are supported by at least three "official" actions that *are* "binding": (i) the [redacted], which Phillips did not know about when he wrote his opinions (Lazerow Dec. Ex. 12; Lazerow Supp. Dec. Ex. 17 at 154:10–155:22, 359:3–363:4 ("not just anyone can send one of those letters")); (ii) FDA's clearance of Iconocare's remanufactured EndoWrist (signed by the same FDA official who signed the [redacted]); and (iii) creation of a new product code.

but because Phillips *does not know what Iconocare does.* The only information Phillips relied on for his understanding of Iconocare's device – FDA's publicly-available clearance letter with a three-page summary of the device[6] – does *not* include any details about Iconocare's modifications. Opp. at 11; Lazerow Dec. Ex. 1 ¶ 120 & n.46. (Phillips also ignores that that document uses the product code (QSM) defining the device as "remanufactured." *Id.*) Phillips never reviewed the documents that contain the details of Iconocare's activities, such as Iconocare's full 510(k) application or [redacted]. Those documents are in the record and could have been available for Phillips' review had SIS chosen to supply them or had Phillips asked for them. But they did not. Phillips is not otherwise privy to Iconocare's activities, and therefore lacks the information needed to assess whether the specific modifications that Iconocare makes are in fact "remanufacturing." Without salient details, Phillips has insufficient facts to which to apply his supposedly "extensive experience," Opp. at 10, in opining on the legal consequences of those facts.

Recognizing that Phillips has this critical gap in knowledge, SIS argues that "knowing the 'details of the activity' Iconocare performed or that FDA assessed is unimportant and unnecessary." *Id.* at 9. But again, merely saying this does not make it so. And both SIS and Phillips have acknowledged that FDA makes its determination about whether a company's activities amount to remanufacturing by focusing "on how those activities have changed the device": "That is, whether the finished device, as a result of being serviced or repaired, has been 'significantly' changed in terms of 'performance or safety specifications, or intended use.'" Opp. at 3 n.4 (citing Lazerow Dec. Ex. 1 ¶¶ 56, 68); *see also* Lazerow Supp. Dec. Ex. 17 at 261:11–20.

SIS cannot satisfy its burden by pointing to the opinion Phillips offered in his rebuttal report that the product code FDA created for a remanufactured instrument in connection with its clearance of Iconocare's 510(k) application "is not evidence of an FDA determination that the activities described in the 510(k) submission constitute remanufacturing." Opp. at 9. Phillips has no basis for reaching such a conclusion. He knows virtually nothing about the activities described in Iconocare's 510(k) submission, and thus he has no basis to opine on why FDA created the product code, assigned it as a

[6] FDA, 510(k) Clearance Letter for K210478, https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf.

"remanufactured device," or viewed Iconocare as a remanufacturer. Nor does SIS justify the fact that, although Phillips ordinarily consults FDA product codes as a regulatory consultant, he did not do so here. Lazerow Supp. Dec. Ex. 17 at 38:9–12, 81:6–22. And even if Phillips were right that the product code is not evidence that FDA determined Iconocare's activities are remanufacturing, it certainly is not evidence to the contrary. [redacted] *See, e.g.*, Lazerow Dec. Ex. 13 at -0534–35. And Phillips' effort to dismiss the product code in his rebuttal report cannot excuse his broad refusal to grapple with the rest of "the great weight of the evidence that contradicts his conclusion." *Smith*, 936 F.3d at 558–59; *see also Bextra*, 524 F. Supp. 2d at 1176.[7]

E. Phillips' Opinion that Intuitive's Customer Communications Were False and Misleading is Unreliable.

SIS has not demonstrated the admissibility of Phillips' opinion that "Intuitive Surgical's customer communications alleged in SIS's Complaint and court filings are simply false and misleading." *First*, SIS does not dispute that a number of the allegations cited by Phillips do not consist of statements made by Intuitive, but rather are SIS's legal conclusions and characterizations of Intuitive's communications. *See* Lazerow Dec. Ex. 1 ¶ 99 (quoting SIS Complaint ¶¶ 123–25, 97–98). Those allegations cannot support Phillips' opinion. *See State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013) ("[A]n expert's proffered opinion that merely parrots information provided to her by a party is generally excluded.").

Second, Phillips admitted in his deposition that one of Intuitive's alleged customer communications that he characterizes in his report as "false or misleading" was actually *truthful*. *Compare* Lazerow Dec. Ex. 2 at 418:18–420:3 *with id.* Ex. 1 ¶ 4(iv). SIS does not even attempt to defend Phillips' abandonment of this part of his opinion. Opp. at 11–12. In fact, Phillips' reversal on

[7] SIS's theory that FDA mistakenly assigned the new product code, Opp. at 10 n.8, appears nowhere in Phillips' reports, and SIS cites no evidence that FDA made a mistake or failed to follow its own guidance. In fact, FDA's guidance (which Phillips was not aware of) contradicts SIS's theory. Contrary to SIS's suggestion, *id.*, FDA does not create a new product code *only* when a proposed device is found not substantially equivalent (NSE). FDA also creates a new code when a device "incorporates new technology that raises new questions of safety and effectiveness" and "for tracking purposes for a specific technology or device area." FDA, Medical Device Classification Product Codes, at *6, https://www.fda.gov/media/82781/download.

this point undercuts the reliability of his entire opinion, because he is not offering tailored testimony about *some* of the material he reviewed about Intuitive's communications but instead purports to address it all collectively. *See* Lazerow Dec. Ex. 1 ¶ 4(iv).

Third, SIS provides no explanation for Phillips' departure from his usual methodology: that he wants to see the context of a communication before determining whether it was false or misleading. *See* Opp. at 11–12; Lazerow Dec. Ex. 2 at 417:3–418:17; Lazerow Supp. Dec. Ex. 17 at 420:11–18. Instead, SIS falls back on the generic argument that the "flaws in Mr. Phillips' analysis of Intuitive's customer communications can be adequately addressed through cross-examination at trial, rather than exclusion." Opp. at 12. The Ninth Circuit has made clear that this facile dodge cannot be used to escape *Daubert* scrutiny in the face of a meaningful reliability challenge. *See United States v. Holguin*, 51 F.4th 841, 854–55 (9th Cir. 2022) (a district court's conclusion that a challenge goes to "weight, not admissibility" is "not a reliability finding") (citing *Valencia-Lopez*, 971 F.3d at 899 ("Dismissing an argument as 'going to the weight, not admissibility, of [the expert's] testimony' is not a reliability determination.")).

Finally, Phillips' opinion on this subject is tied up with his opinions addressed above about whether FDA clearance is required for EndoWrist remanufacturing activities. The defective "methodologies" and dearth of facts on which those opinions are based also infect Phillips' opinion on whether Intuitive's statements on those same subjects were false or misleading. Moreover, SIS does not even attempt to reconcile the self-contradictory nature of Phillips' opinion that FDA's definition of "remanufacturing" is "not clear and cannot be used to consistently and reliability [sic] differentiate remanufacturing from servicing" with his opinion that Intuitive was "objectively unreasonable" to assert that FDA clearance was needed. Lazerow Dec. Ex. 5 at pt. II; *id.* Ex. 1 ¶ 125. Without an explanation, this "self-contradicted" opinion must be excluded. *Loy*, 558 F. Supp. 3d at 408.

III. CONCLUSION

For these reasons, and for the reasons stated in Intuitive's opening brief, the Court should grant Intuitive's Motion and exclude the opinions of Philip J. Phillips.

DATED: May 11, 2023

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